K080555

iVu

JUN - 3 2008

Section 2 - 510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

1. Contact Person

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2. General Information

Name:	iVu Imaging Corporation
Trade Name:	Sofia™ (ATUS) Imaging Device
Classification Name:	Transducer, Ultrasonic, Diagnostic
Classification:	This device is classified by the Reproductive, Abdominal and Radiological Devices into Class II, (21 CFR 892.1560 Ultrasonic pulsed echo imaging system and 892.1570 Diagnostic ultrasonic transducer)

3. Device Description

The Sofia™ (ATUS) device consists of three (3) major components 1) an exam table which houses the examination pyramid, motor drive assembly, fluidics evacuation and storage system, and the power supply assembly 2) an ultrasound probe which is embedded into the exam pyramid on one end and connected to the ultrasound system on the other end, 3) an ultrasound system that acquires and stores the ultrasound data from the patient's breast exam.

The Sofia™ (ATUS) device, as well as, the two predicate devices (Trade Name: FFBU Diagnostic Ultrasound System manufactured by U-Systems, Inc (K032640), Trade Name: ABUS Diagnostic Ultrasound System manufactured by U-Systems, Inc (K052355) utilize standard B-Mode grayscale ultrasound to achieve their intended use. Both the Sofia™ (ATUS) device and the U-Systems FFBU and ABUS systems use automated linear ultrasound transducers to evaluate breast tissue. The Sofia™ (ATUS) device, as well as, the U-Systems FFBU and ABUS systems all use automated linear transducers to acquire serial 2D grayscale images of the entire breast. These 2D images can then be reviewed by a radiologist to determine if any abnormal anatomical features are present in the patient's breast. The Sofia™ (ATUS) system utilizes the same mode of operations, general operating principals, as well as, general and specific indications for use as the predicate devices described above.

4. Intended Use

The Sofia™ (ATUS) device is indicated for use as a B-mode ultrasonic imaging system for imaging of a patient's breast when used with an automatic scanning linear array transducer. The device is not intended to be used as a replacement for screening mammography.

5. Substantial Equivalence Comparison

The iVu Sofia™ (ATUS) device is substantially equivalent to the following devices with respect to intended use, design, materials and construction:

- The FFBU Diagnostic Ultrasound System manufactured by U-Systems, Inc (K032640)
- The ABUS Diagnostic Ultrasound System manufactured by U-Systems, Inc (K052355).

Section 4 of this 510K shows much more detail relative to specific similarities and differences between the Sofia™ (ATUS) system and the predicate devices; also a table is provided for clarity. The Sofia™ (ATUS) device and the predicate devices are substantially equivalent in their intended uses and / or device design. In addition to the similar intended use, all of the predicate devices utilize B-Mode Grayscale Ultrasound to achieve their intended use. Both the Sofia™ (ATUS) and the predicate devices use automated linear ultrasound transducers to image breast tissue. Both the Sofia™ (ATUS) device and the predicate devices use commercially available FDA 510K approved ultrasound systems to acquire ultrasound images.

The Sofia™ (ATUS) system uses the GE LOGIQ e (K050126). The U-Systems ABUS and FFBU systems use the Siemens Antares DUS (K023720). Refer to **Attachment I** for a copy of the GE Medical Systems 510K (K050126).

A brief discussion of the similarities and differences between the Sofia™ (ATUS) device and its predicate devices is provided below.

Similarities

- Similar to the Sofia™ (ATUS), the U-Systems FFBU system uses an automated linear transducer to acquire serial 2D images of the patient's breast. The FFBU system uses a commercially available FDA 510K approved ultrasound system to acquire and process B-Mode grayscale images of a patient's breast.
- Similar to the Sofia™ (ATUS), the U-Systems ABUS system uses an automated linear transducer to acquire serial 2D images of the entire patient's breast. The ABUS system uses a commercially available FDA 510K approved ultrasound system to acquire and process B-Mode grayscale images of a patient's breast.

Differences

- The Sofia™ (ATUS) system uses an FDA 510K approved linear transducer manufactured by GE Medical Systems. The U-Systems ABUS device uses a custom automated linear transducer. The transducers listed above are all broad band transducers with frequency ranges between 7MHZ and 11MHZ.
- The Sofia™ (ATUS) system positions the patient in a prone position lying on its examination table with the breast in a pendulous position within the pyramid shaped dome. The U-Systems ABUS and FFBU devices position the patient in a supine position and use the transducer housing of its devise to compress the breast tissue between the transducer face and the thoracic wall.
- iVu's pendulous position of the breast in a fluid environment eliminates the need for breast compression. No new issues of safety or efficacy are created.

6. Summary of Studies

The function and performance of the Sofia™ (ATUS) system have been evaluated through non-clinical design verification and validation tests. Testing included mechanical performance evaluations and simulated use tests. The results of the Sofia™ (ATUS) systems performance evaluations demonstrate that the Sofia™ (ATUS) device design is well suited for its intended use.

iVu Imaging completed mechanical performance evaluations to verify that the Sofia™ (ATUS) system meets predetermined specifications, conforms to product performance requirements, and supports the compatibility of internal components. Test results, as documented in Section 7, support that the Sofia™ (ATUS) system meets the predetermined specifications and performance requirements for its intended use.

Additional testing of The Sofia™ (ATUS) device will be performed by an independent testing laboratory (**Intertek Testing Services NA, Inc)** and must demonstrate conformance with the IEC 60601 series of electrical and electromagnetic safety standards before commercial distribution begins. In Section 7 of this document, under "ELECTRICAL SAFETY TESTING" is a signed certification by the President of iVu attesting to the fact that such testing will occur prior to commercialization. The following specific standards will be tested.

Document Number	Description
IEC 60601-1	IEC 60601-1 Issue 1988/12/01 Ed:2 Medical Electrical Equipment Part 1: General Requirements for Safety; (Amd. 1-1991) (CENELEC EN 60601-1: 1990) (Amd. 2-1995) (Corrigendum-1995)
UL 60601-1	UL 60601-1 UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety Issued: 4/25/2003 Ed: 1
CAN/CSA-C22.2 No. 601.1-M90	CAN/CSA-C22.2 No. 601.1-M90 Canadian Electrical Code, Part I. Rev. 1999
IEC 60601-1-2	IEC 60601-1-2 Issued: 2001/09/30 Ed:2 Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Req. and Tests

In Section 7, Bench testing included testing performed in-house, as well as, an opinion from an expert in the field of acoustic sonography who also performed and documented acoustical output testing. In-house testing, the opinion, and acoustic testing demonstrate the safety and effectiveness of the Sofia (ATUS) system.

7. Conclusion (statement of equivalence)

The data and information provided in this submission supports a substantial equivalence determination, and, therefore, 510(k) premarket notification clearance of the Sofia™ (ATUS) Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2008

iVu Imaging Corportaion
% Mr. Daniel W. Lehtonen
Sr. Staff Engineer – Medical Devices
Intertek Testing Services
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TWINSBURG OH 44087

Re: K080555
Trade/Device Name: Sofia™ Automated Tomographic Ultrasound (ATUS)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: ITX and IYO
Dated: May 16, 2008
Received: May 19, 2008

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Sofia™ Automated Tomographic Ultrasound (ATUS), as described in your premarket notification:

Transducer Model Number

12L-RS

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain

other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Statement

510(k) Number: K080555

Device Name: Sofia™ Automated Tomographic Ultrasound (ATUS)

Indications for use:

The Sofia™ (ATUS) device is indicated for use as a B-mode ultrasonic imaging system for imaging of a patient's breast when used with an automatic scanning linear array transducer. The device is not intended to be used as a replacement for screening mammography.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080555

Diagnostic Ultrasound Indications for Use Form

510(K) Number: **K080555**

Device Name: Sofia™ Automated Tomographic Ultrasound (ATUS) device
Ultrasound probe – GE 12L-RS

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Breast)		P								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peritherial Vascular										
Laparoscopic										
Musculo0skeletal Conventional										
Musculo0-skeletal Superficial										
Other (specify)										

N=New indication: P=Previously Cleared by FDA; E= Added Under Appendix E

Additional Comments: The iVu Imaging Sofia™ Automated Tomographic Ultrasound (ATUS) device is intended for ultrasonic breast examinations.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080555